

Recruitment to Clinical Trials



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Agenda

- Barriers to recruitment
- Recruitment strategies
- NIH resources

Introduction

- Validity of clinical research studies are dependent on:
 - Recruitment of adequate numbers of a required participant population
 - Retaining participants
 - Ensuring the protocol is followed

Recruitment Statistics

Up to 80% of all trials miss their enrollment deadlines

45% of all delays in clinical trials can be attributed to poor patient recruitment

Barriers to Participation

- CLINICIAN
- SYSTEM
- PATIENT



Clinician Centered Barriers...

- Time Constraints
- Lack of support staff
- Impact on doctor-patient relationship
- Concern for patients
- Clinician bias
- Loss of professional autonomy

...Clinician Centered Barriers

- Obtaining consent
- Poor financial reimbursement
- Lack of interest in the specific research question
- Fear of Not Being Kept Informed about Patient's Care

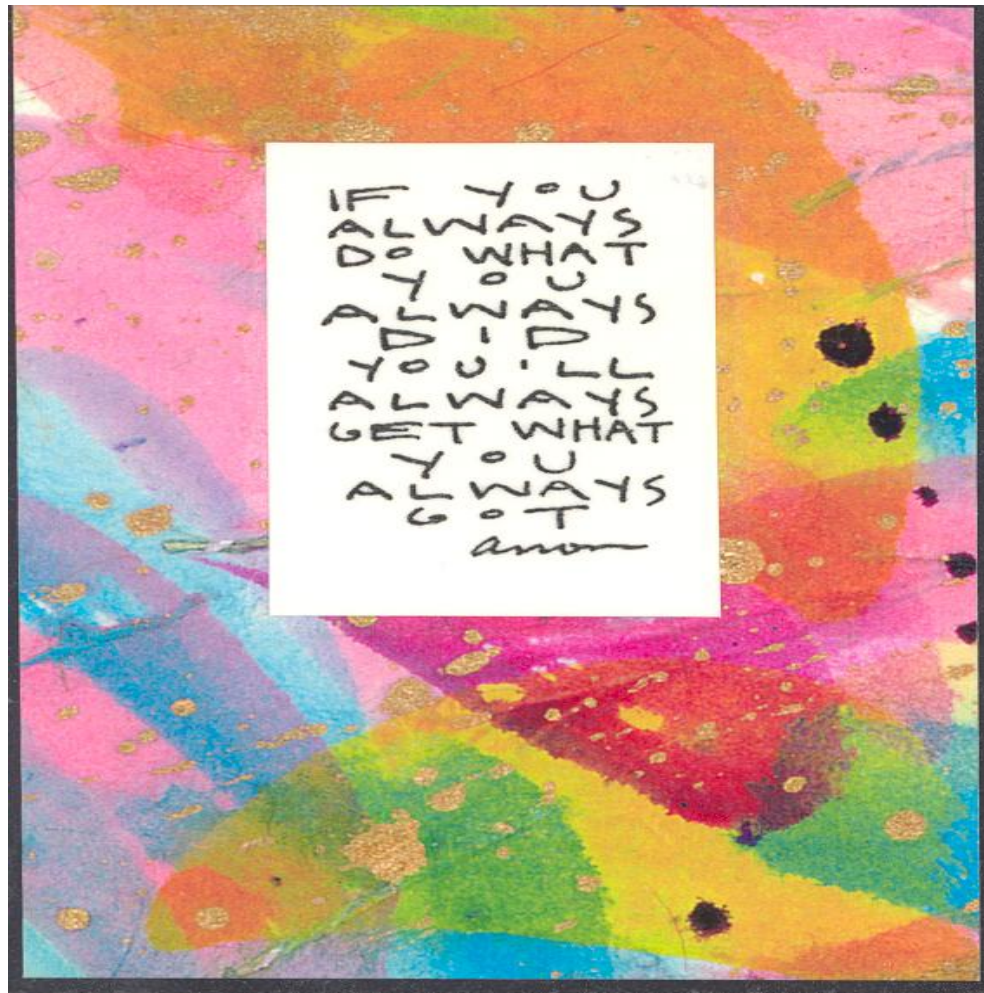
System Barriers

- Protocol Issues
- Expense
- Competition
- Sponsor-centered
 - Adequate Funding
 - Site Selection
 - Investigator Selection

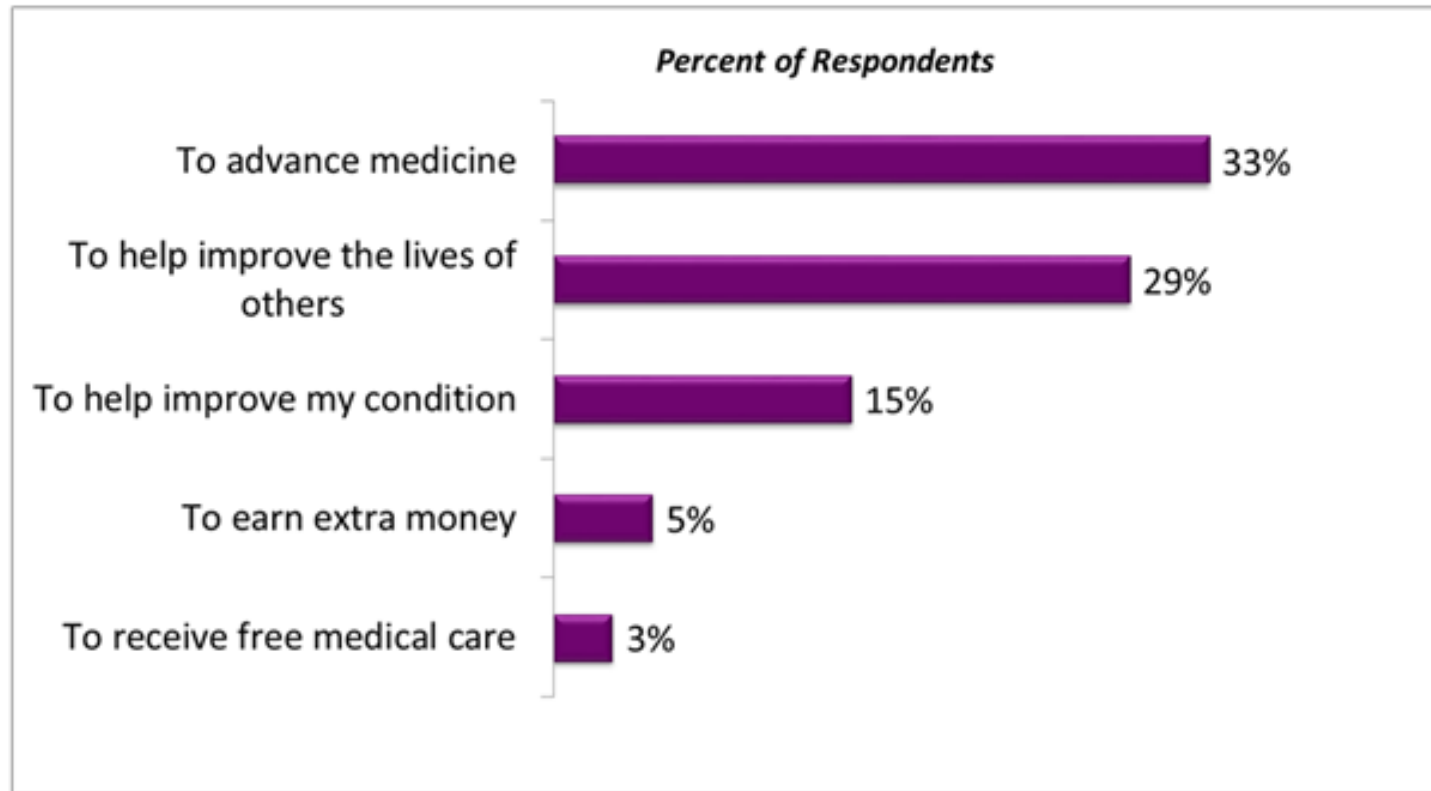
General Population Barriers

- Lack of Awareness
- Mistrust
- Demands of the study
- Preference for a particular treatment
- Concerns about side effects
- Comfort level with physician
- Language and literacy
- Loss of privacy
- Portrayal as guinea pig
- Misperceptions
- Geographical Limitations
- Financial Considerations

STRATEGIES



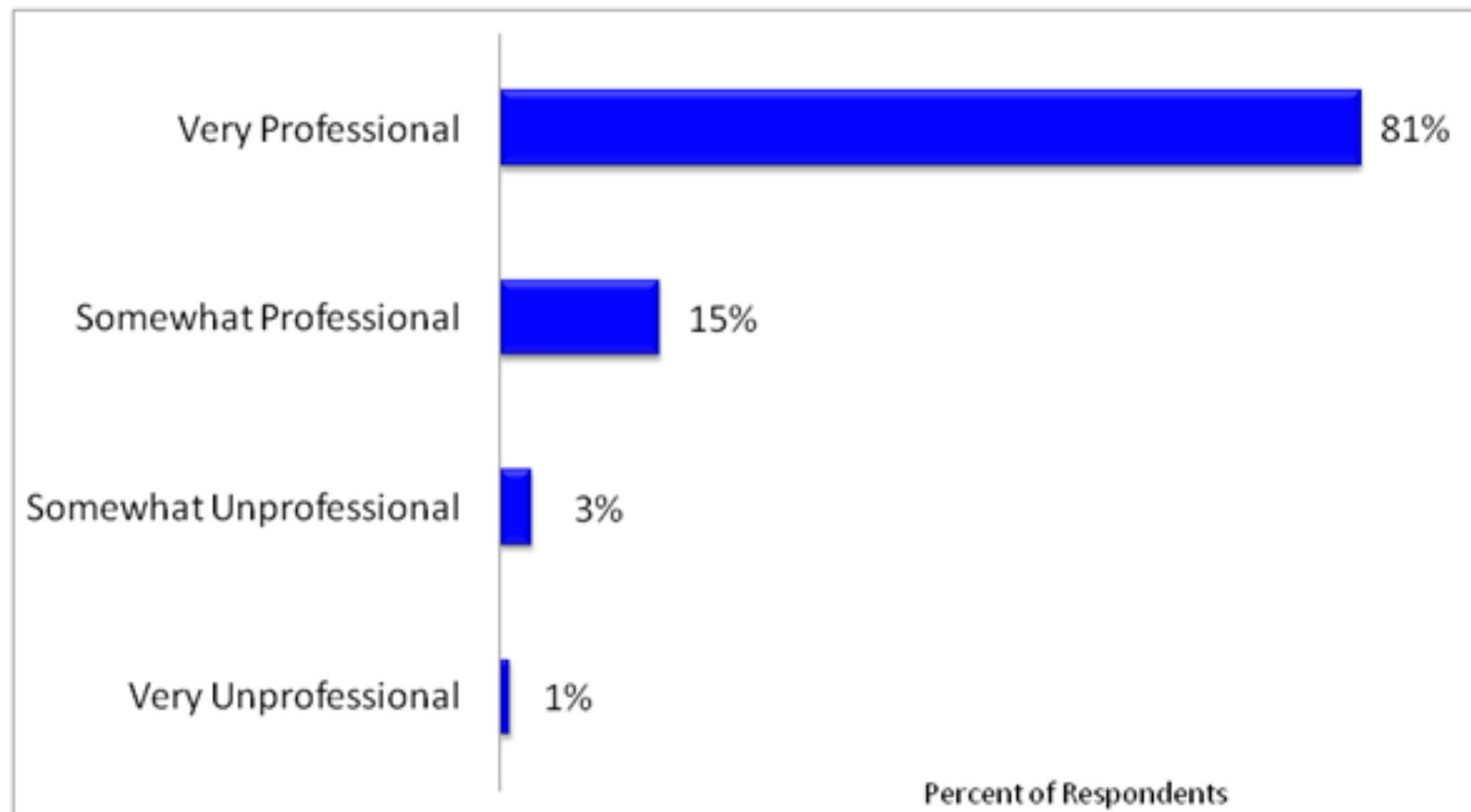
Top Reasons People Choose to Participate in Clinical Trials



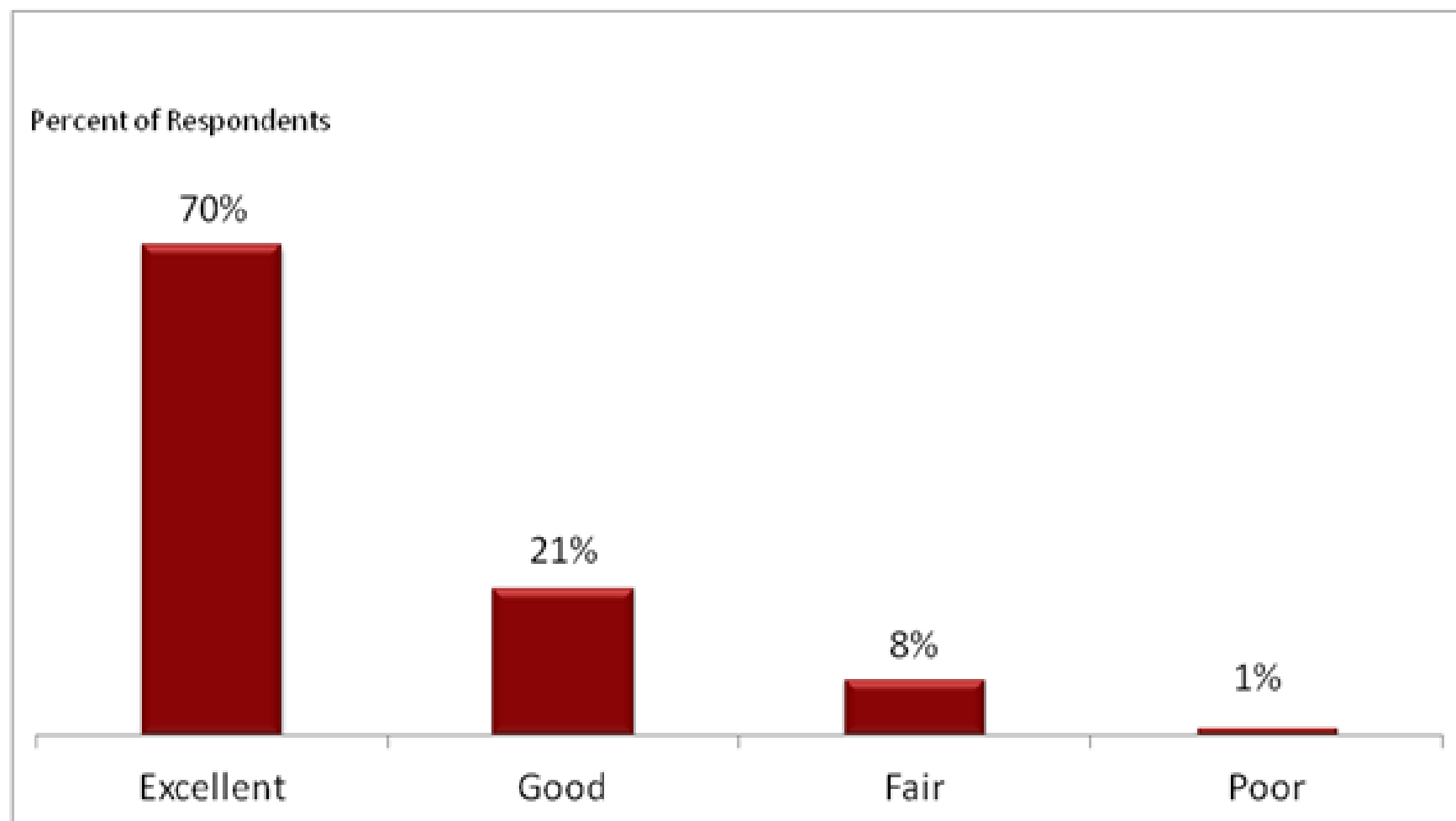
Source: CISCRP, 2013; N=5,701 people worldwide

Center for Information and Study on Clinical Research Participation (CISCRP)

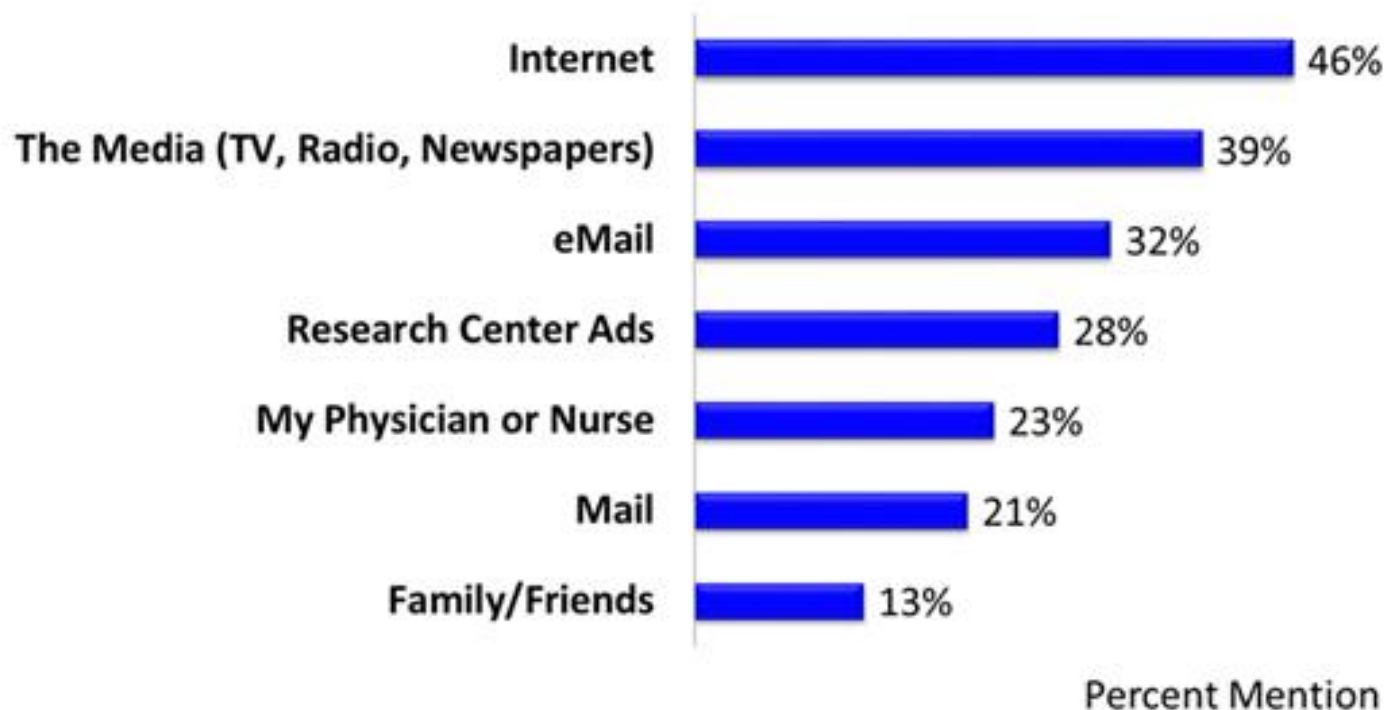
Study Volunteer Ratings of Clinical Research Staff Professionalism



Study Volunteer Ratings of the Quality of Care that They Received in a Clinical Trial



Top Ways that People Report Finding out About Clinical Trials



Source: CISCRP, 2013; N=5,701 people worldwide

Other Strategies

- Protocol specific
 - Length of Study
 - Choice of Control Groups
 - Inclusion/Exclusion Criteria
 - Procedures Performed
 - Maintain accurate screening logs
- Other clinics
- Advocacy groups

Recruitment Plan

- Study population should be appropriate for the research question being asked (representative of the study population with the disease)
- Inclusion/exclusion criteria should be explicit
 - The more stringent your exclusion criteria the more difficult it will be to recruit
 - Lack of appropriate exclusion criteria leaves the study open to potential confounders
- Inclusion of Women and Minorities—Regulatory
- Added scrutiny for recruiting vulnerable populations

RETENTION



Retention of Subjects

- Keeping subjects in the study
- Key factors to success
 - Protocol Design
 - Patient Education
 - Informed “Decision”
 - Customer Service

Summary

- Several barriers
- Strategies to overcome barriers
- Recruitment & retention are related and affect the validity of the study results
 - Organized efforts should be made throughout the study to enhance both
- Plan up front for recruitment & retention

Resources Available Through the NIH CC

- Office of Patient Recruitment (OPR)
- Clinical Research Volunteer Program (CRVP)
- Contact information
 - Dinora Dominguez
 - Mandy Jawara
 - 301-496-4763

OPR Services

- Toll-Free Telephone Information and Referrals Service in English and Spanish
- A critical first step - Telephone Prescreening
- Recruitment Consultation

FileEditViewHistoryBookmarksToolsHelp

NIH Clinical Center: Patient R... x +

clinicalcenter.nih.gov/recruit/index.html

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Patient Recruitment at the NIH Clinical Center

Research volunteers are partners in discovery at the Clinical Center, the nation's clinical research hospital. Clinical research is medical research involving people. The Clinical Center's mission is to rapidly translate scientific observations and laboratory discoveries into new ways to diagnose, treat and prevent disease. More than 480,000 individuals from around the world have participated in clinical research at the Clinical Center since the hospital opened in 1953.

Research participants include healthy volunteers and patient volunteers.

A [healthy volunteer](#) is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention. Research with healthy volunteers is designed to develop new knowledge, not to provide direct benefit to study participants. Healthy volunteers have always played a vital role in medical research.

A patient volunteer has a known health problem and participates in research to better understand, diagnose, treat, or cure that disease or condition. Research procedures with a patient volunteer help develop new knowledge. These procedures may or may not benefit the study participants.



Search The Studies

You can search the collection of research studies being conducted at the NIH Clinical Center at [Search the Studies](#).

In addition, [clinicaltrials.gov](#) provides patients, family members, and members of the public easy and free access to information on clinical studies for a wide range of diseases and conditions.

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<http://clinicalcenter.nih.gov/recruit/>

CRVP Services

- Program began in 1954
- Objectors to the war were given the opportunity to substitute research for military service
- Wanted to be referred to as “NORMAL”
- Services:
 - Reaching Healthy Volunteers
 - Recruit, Register, and Compensate Research Volunteers
 - Compensation Guidelines on Remuneration

ResearchMatch

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As of right now there are:

volunteers

67,428

researchers

2,228

studies

390

institutions

97

[see more!](#)

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Welcome to researchmatch!

Want a chance to make a difference? Here it is.

Research positively impacts the lives of millions of people every day, but research needs **YOU** to keep it moving forward. All too often studies are forced to end early because there aren't enough volunteers which means many important questions go unanswered and treatment options remain limited. ResearchMatch helps solve this problem by matching people who want to participate in research with researchers who need

What is ResearchMatch?



Questions

